



# Conflict of Interest in Research

## Policy Changes and Rollout

Presented by: Research Integrity & Oversight Office

# Change is Coming... When? Why?

- ICON COI module “soft launch” May/June 2018
- Changes in policy align with new online system:
  - Efficiency/Streamlining of process
    - Reduced administrative burden for Deans/Chairs (e.g. signatory requirements)
    - Reduced administrative burden for researchers (e.g. rolling due dates)
    - Concentration on highest risk disclosures
  - Minimization of risk to researchers and university
  - Alignment of best practices with research institutions across the country

# Reminders

- DOR Policy Applies to Investigators
  - The project director or principal investigator, and any other persons, regardless of title or position, who are responsible for the design, conduct, and reporting of research activities funded or proposed for funding
    - See policy guidance, pg 3
    - \*New: applies to unfunded research under certain conditions
- **Research** COI Certification/Disclosure only
  - Does not replace/negate:
    - SAM 02.A.08 – Consulting and Paid Professional Service
    - SAM 02.A.09 – UH System Conflict of Interest Policy

# Reminders

*Conflicts of interest can arise out of the fact that a mission of the University is to promote public good by fostering the transfer of knowledge gained through University research and scholarship to the private sector. Two important means of accomplishing this mission include consulting and the commercialization of technologies derived from University research. It is appropriate that individuals be rewarded for their participation in these activities through consulting fees, sharing in royalties arising from the commercialization of their work, ownership and/or other associations with spin-off companies.*

*The cornerstone for managing conflicts of interest is  
transparency*

# Reasons for Change

- **Federal Requirement**
  - Explicitly stated in federal regulations; no option
- **Compliance Gap**
  - Gap created over the course of time, as investigator funding changes or non-federal agencies require adherence to federal regulations
- **Best Practice**
  - Instituted by high number of peer institutions locally and/or nationally to meet one or both of the above
- **Reduced administrative burden**
  - For researchers, signatories, COI committee



# Change: Who Must Disclose?

- In addition to investigators associated with monetary awards, research team financial interests indicated as part of the IRB/IACUC review process will require disclosure, even if project is unfunded.

Federal requirements,  
best practice.

# Changes in Disclosure

- Now a consistent threshold value for significant financial interest, *regardless of funding source*. In most cases, \$5000.

Compliance gap, best practice

- Exception – ANY equity interest in a non publicly-funded entity (ex: start-up company)

Federal requirement, unchanged

- Disclosure of all significant financial interests meeting threshold that are reasonably related to institutional duties (institution determines relatedness to research)

Federal requirement

# Change: Training Requirements

- All investigators must complete COI CITI training, regardless of funding source.
- Valid for 4 years, then refresher course

Compliance gap, best practice



# System Change: Rolling Due Dates

Reminder: Certifications are due:

- Annually
- Within 30 days of discovering or acquiring a new significant financial interest
- At time of new award
  - Research certification sent by DOR upon receipt of a new award. (Taking that award into consideration, if nothing has changed, simply log in, check box, and move forward)
- Annual certifications will now be on a rolling due date – i.e. *not* all on October 1.

# Other Features to Reduce Admin Burden

- Automated email notifications
- Automated reminders
- Access to ICON 24/7 from any browser
- All records maintained securely online
- Fill out full certification/disclosure ONCE – make changes as needed but not a new form “from scratch” each time. Keeps ongoing, up to date record with no annual duplication

# Signatory Process Changes

## Signatory/acknowledgment required:

- Only when a financial interest meeting threshold is disclosed (all others are auto-acknowledged)
- Only from immediate level above discloser - typically Department Chair; see policy for exceptions
- In most cases, secondary level (typically Deans) acknowledgement no longer required **at the time of disclosure**, *however*:
  - Deans become an active part of the process once a conflict of interest is determined that must be managed, and
  - A report is available to Deans at any time that will allow them to view the statuses of their college's certifications/disclosures/conflicts under management at any time

# Management Plan Monitoring for COIs

- Per current policy (unchanged):  
*“Departments, Colleges, and Center Directors are responsible for ensuring that required management plans are carried out and monitored until the completion of the research”*
- A monitor will be assigned within the ICON system for each finalized management plan. (Typically Chair, but can be delegated.) Verification of compliance with plan at least semi-annually

Compliance gap, best practice

# Rollout

- Annual certification for 2018 still due October 1, *unless...*
- If a new award is received *prior to October 1*, applicable investigators will receive notification to enter annual certification into ICON, taking new award into account.
- COI office to provide access per award
- Previous certification/disclosure can be provided for reference
- COI office to work hand-in-hand with these individuals
- Compliance with new policy required once first submission is made in ICON; until then, current policy applies



# Training Opportunities

- Department-wide trainings will be provided prior to October 1 annual certification
- Your thoughts on training as we initiate soft roll-out?
  - One-on-one/small group trainings
  - “Open house” hours set in E. Cullen
  - Other – very flexible and open to suggestions

# Contacts/Questions

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THANK YOU for your time and feedback!

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